

Attorney Docket No.: 47234.5005/00US  
Application No. 10/575,763  
Amendment Dated: October 12, 2007  
Reply to Office Action Dated: April 12, 2007

## **R E M A R K S**

Applicant respectfully requests reconsideration and reexamination of the present application in light of the foregoing amendments and following remarks.

### **1. Status of the Claims**

Claims 1-16 are pending. Claims 1-10 and 16 stand withdrawn as directed to a non-elected invention. Claims 11-15 stand rejected. Claims 17 is added by entry of the present amendment.

### **2. Support for the Amendments**

Amendments are made without prejudice or disclaimer of the canceled subject matter. Applicant reserves the right to file a continuing or divisional application on any subject matter canceled by way of amendment. The subject matter added by amendments is supported throughout the specification as filed. Specifically, support for new claim 17 can be found, for example, at Table 2, Example 2, and the accompanying text. Antigen-antibody “binding” is supported throughout the specification, for example, at page 12, line 23.

### **2. Status of the Drawings**

Applicants note with appreciation the indication that the drawings filed April 13, 2006, are accepted.

### **3. Acknowledgement of Priority Documents**

Applicant appreciates the indication of receipt of the Certified Priority Document filed in the above-identified application.

### **4. Acknowledgement of the Information Disclosure Statement**

Applicant further notes the return of the initialed copy of the PTO-1449 forms filed with the Information Disclosure Statements dated April 13, 2006, and February 28, 2007.

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**5. Rejection of the Claims Under 35 U.S.C. § 112, Second Paragraph**

Claims 11-15 stand rejected under 35 U.S.C. § 112, second paragraph, as being indefinite for failing to particularly point out and distinctly claim the subject matter which applicant regards as the invention. Specifically, the Office alleges that the term “reaction” is indefinite.

To expedite prosecution, claim 11 is amended in the present response to recite “binding” instead of “reaction.” The rejection may now be withdrawn.

**6. Rejection of the Claims Under 35 U.S.C. § 112, First Paragraph**

Claims 11-15 stand rejected under 35 U.S.C. § 112, first paragraph, on the grounds that the specification, while being enabling for a method for prognostic evaluation of P-LAP positive carcinomas, allegedly does not reasonably enable prognostic evaluation of all carcinomas.

To expedite prosecution, claim 11 is amended in the present response to recite that the method comprises contacting *P-LAP positive* carcinoma tissues obtained from carcinoma patients with an anti-P-LAP antibody. The rejection may now be withdrawn.

**7. Rejection of the Claims Under 35 U.S.C. § 102**

Claims 11-15 stand rejected under 35 U.S.C. § 102(a) as being anticipated by Suzuki, *et al.*, *Clin. Cancer Res.* 9: 1528-34 (April 2003) (“the Suzuki reference”). Applicant traverses the rejection as it applies to the amended claims. Applicant further respectfully requests that the Office clarify and elaborate its rationale for applying the Suzuki reference as art under 35 U.S.C. § 102(a), should the Office maintain the rejection. *See* 35 U.S.C. §§ 102(a), 102(b), 119(a), 120, and 365.

The Suzuki reference does not disclose all the elements of the claimed method and, as such, does not properly anticipate the claimed invention. In this case, the presently claimed method comprises: (a) contacting P-LAP positive carcinoma tissues obtained from carcinoma patients with an anti-P-LAP antibody, (b) measuring the intensity of the specific antigen-antibody binding between P-LAP present in the carcinoma tissues and anti-P-LAP antibody, and (c) correlating the intensity of the specific antigen-antibody binding with prognosis of carcinoma. Giving the terms of the claim their broadest possible interpretation in light of the specification, to

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correlate binding with a “prognosis” means that binding is correlated with “a prediction of the probable course and outcome of a disease” or “the likelihood of recovery from a disease.” *See, e.g.*, The Free Dictionary, *at* <http://www.thefreedictionary.com/prognosis> (last accessed May 10, 2007).

The Suzuki reference teaches contacting P-LAP positive carcinoma tissues obtained from carcinoma patients with an anti-P-LAP antibody. Suzuki teaches that the intensity of the specific antigen-antibody binding between P-LAP present in endometrioid adenocarcinoma tissues and anti-P-LAP antibody correlates with the degree of endometrioid adenocarcinoma at the measurement time. *See* Suzuki, Western blot at Fig. 1, panel F, for example. The Office alleges that the Suzuki reference teaches increased binding between an anti-P-LAP antibody and P-LAP “wherein increased expression correlated with increased grade [of endometrioid adenocarcinoma] *or* prognosis.” Office Action, page 6, first paragraph (emphasis added). The Suzuki reference, however, does not teach that correlating the intensity of the specific antigen-antibody binding will provide a *prediction* of the outcome of endometrioid adenocarcinoma or a likelihood of *recovery* from the same. Accordingly, the Suzuki reference does not teach “a step of correlating the intensity of the specific antigen-antibody binding with *prognosis* of carcinoma,” as claimed.

To clarify this distinction between the Suzuki reference and the claims, Applicant provides new claim 17, which recites that the intensity of the specific antigen-antibody binding between an anti-P-LAP antibody and P-LAP is correlated with a ten-year disease-free survival rate (DFS) of the patient. The Office has provided no evidence that the Suzuki reference either explicitly or inherently teaches such a correlation or suggests the recited correlation.

Accordingly, the claims are believed to be free of the cited art, and Applicant urges an indication of allowability over the same.

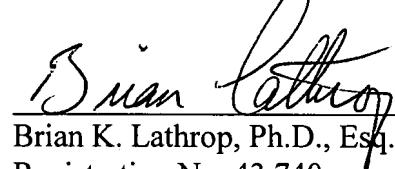
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**CONCLUSION**

If there are any other fees due in connection with the filing of this response, please charge the fees to our Deposit Account No. 50-0573. If a fee is required for an extension of time under 37 C.F.R. § 1.136 not accounted for above, such an extension is respectfully requested and the fee should also be charged to our Deposit Account. If any issues remain outstanding, the Examiner is invited to contact the undersigned attorney, who signs in his authority under 37 C.F.R. § 1.34(b).

Respectfully submitted,

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Dated: October 12, 2007